



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/538,716

06/10/2005

Toshiya Fujisato

AKA-0286

6913

23599

7590

07/28/2006

MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
2200 CLARENDON BLVD.
SUITE 1400
ARLINGTON, VA 22201

EXAMINER

MAKAR, KIMBERLY A

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 07/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/538,716	Applicant(s) FUJISATO ET AL.	
	Examiner Kimberly A. Makar	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/10/2205</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claim 1 is objected to because of the following informalities: Claim 1 uses the word "microwave" which should be plural "microwaves". Appropriate correction is required.
2. Claim 4 is objected to because of the following informalities: Claim 4 uses the word "microwave" which should be plural "microwaves". Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 2 uses the phrase, "small proportion" of an organic solvent. The term, "small proportion" is a subjective term that is not defined in the specification. What proportions are encompassed within the terminology, and which are excluded? Is the proportion small compared to the total solution volume, or tissue being treated? A skilled artisan would be unable to determine the metes and bounds of the claimed invention.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-3, 5, 7-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Anderson et al (US Patent No. 5,571,216). Claims 1-3, 5, 7-8 states a method of treating a native tissue of mammalian origin comprising immersing the tissue in a treating solution, and irradiating the tissue with a microwave while maintaining the temperature of the tissue in the range between 0°C and 40°C (claim 1) where in the treating solution is water, a hypertonic, hypotonic, detergent, enzyme solution, a liquid medium or a mixture thereof with a small proportion of an organic solvent (claim 2). The method is further limited to include a chemical fixation comprising a treating solution containing glutaraldehyde (claim 3). The native tissue to be treating includes vascular tissue, heart valve, heart sac, cornea and dura (claim 5). The native tissue is further limited to be treated as an organ or part there of (claim 7). The method further comprises the step of washing with a fresh washing liquid following the irradiation step (claim 8).

7. Anderson et al (US Patent No. 5,571,216) teaches a method of tissue welding comprising immersing the tissue in a welding bath (treating solution) and heating the tissue using a microwave (column 6, lines 1-6) at a temperature of 40°C (Column 8, line 37). Anderson specifically teaches mammalian tissue welding on bovine and porcine

Art Unit: 1636

tissue (column 8, lines 28-43) as well as rabbit tendons and skin (column 9, lines 26-28). Anderson teaches that the welding bath comprises water (column 5, line 30) and that the chemical fixation step comprises a solution that contains glutaraldehyde (column 7, lines 18-29). Anderson teaches that the native tissue to be treated includes vascular vessels as well as parts of whole organs including the gut (Column 1, lines 42-45). Finally, Anderson teaches that the method of treatment further comprises quenching step (ie a washing step following irradiation) (column 8, lines 40-41). Thus Anderson teaches the claimed invention.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Art Unit: 1636

10. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al (US Patent No. 5,571,216) as applied to claim 1 above, and further in view of Kearns et al (US Patent No. 4,963,708). Claim 4 states a method of treating a native tissue of mammalian origin comprising immersing the tissue in a treating solution, and irradiating the tissue with a microwave while maintaining the temperature of the tissue in the range between 0°C and 40°C (claim 1) wherein the tissue is irradiated with microwave at a frequency of 2450 MHz for a net period of time from 1 hour to 1 week.

11. Anderson et al (US Patent No. 5,571,216) teaches a method of tissue welding comprising immersing the tissue in a welding bath (treating solution) and heating the tissue using a microwave (column 6, lines 1-6) at a temperature of 40°C (Column 8, line 37). Anderson specifically teaches mammalian tissue welding on bovine and porcine tissue (column 8, lines 28-43) as well as rabbit tendons and skin (column 9, lines 26-28). Anderson teaches heating the tissue for a period of 1 hour (column 8, lines 37-39) however Anderson does not teach using a microwave at 2450 MHz.

12. Kearns et al (US Patent No. 4,963,708) teaches a method and apparatus for cooking utilizing a microwave and a double-boiler apparatus. Specifically, Kearns et al teaches that, "essentially all domestic microwave ovens operate at 2450 MHz" (Column 1, lines 23-24).

13. The skilled artisan would have been motivated to combine the teachings of Anderson on the method of native mammalian tissue-welding comprising the immersion of tissue in a treating solution and heating the solution in a microwave to a temperature of 40°C for one hour with the teaching of Kearns that all domestic microwave ovens

Art Unit: 1636

operate at the frequency of 2450 MHz because doing so would not require a special (ie more expensive or hard to find) microwave oven in order to perform the method. It would have been obvious to the skilled artisan to combine the teaching of Anderson on the method of native mammalian tissue-welding comprising the immersion of tissue in a treating solution and heating the solution in a microwave to a temperature of 40°C for one hour with the teaching of Kearns that all domestic microwave ovens operate at the frequency of 2450 MHz because using the specific frequency that most microwave ovens already use would allow for easily obtainable and readily available equipment for the artisan utilizing the method of treating native tissue. Given the teachings of the prior art and the level of skill of the ordinary skilled artisan at the time the instant invention was made, it must be considered that said ordinary skilled artisan would have had reasonable expectation of success in practicing the claimed invention.

14. Claims 6 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al (US Patent No. 5,571,216) as applied to claim 1 above, and further in view of Boyce et al (US Patent No. 6,123,731). Claim 6 states a method of treating a native tissue of mammalian origin comprising immersing the tissue in a treating solution, and irradiating the tissue with a microwave while maintaining the temperature of the tissue in the range between 0°C and 40°C (claim 1) wherein the native tissue to be treated is hard tissue including bone, cartilage, and teeth (claim 6) and wherein the native tissue to be treated has been pretreated to facilitate the removal of donor cells (claim 9).

Art Unit: 1636

15. Anderson et al (US Patent No. 5,571,216) teaches a method of tissue welding comprising immersing the tissue in a welding bath (treating solution) and heating the tissue using a microwave (column 6, lines 1-6) at a temperature of 40°C (Column 8, line 37). Anderson specifically teaches mammalian tissue welding on bovine and porcine tissue (column 8, lines 28-43) as well as rabbit tendons and skin (column 9, lines 26-28). Anderson does not teach the native tissue to be treated to include bone, cartilage, or teeth nor does Anderson teach that the native tissue is to be pretreated to facilitate the removal of donor cells.

16. Boyce et al (US Patent No. 6,123,731) teaches a method of tissue welding comprising immersing human bone fragments (see examples 4 and 5) as well as bovine and porcine bones (column 4, lines 1-5) into a treating solution, and heating the tissue using a microwave (column 6, lines 33-43 and column 7 lines 34-36 and claim 28). Boyce also teaches that the bone fragments are demineralized prior to heat treatment by bathing the bone in a 0.6 HCL bath (See examples 1-5).

17. The skilled artisan would have been motivated to combine the teachings of Anderson on the method of native mammalian tissue-welding comprising the immersion of tissue in a treating solution and heating the solution in a microwave to a temperature of 40°C for one hour with the teaching of Boyce et al on the method of tissue welding comprising bone and the pretreatment of the bone to remove all donor cells because to broaden the type of tissue that the method is capable of treating broadens the applicability for treating multiple tissue types allowing for the treatment of more patients with more transplants and implants all utilizing the same treatment method.

Art Unit: 1636

Furthermore, the pretreatment of the tissue to remove donor cells would reduce the likelihood for the generation of an immune response in the patient, but also exposes the collagen fibers allowing for crosslinking between bone sheets (claims 1-4). It would have been obvious to the skilled artisan to combine the teaching of Anderson on the method of native mammalian tissue-welding comprising the immersion of tissue in a treating solution and heating the solution in a microwave to a temperature of 40°C for one hour with the teaching of Boyce on the method of tissue welding comprising bone because the scope of the treatment becomes broader, allowing for the treatment of additional diseases and patients with the same methodology. Additionally, the pretreatment of the tissue to remove donor cells would reduce the likelihood for the generation of an immune response in the patient, but also exposes the collagen fibers allowing for crosslinking between bone sheets (claims 1-4). Given the teachings of the prior art and the level of skill of the ordinary skilled artisan at the time the instant invention was made, it must be considered that said ordinary skilled artisan would have had reasonable expectation of success in practicing the claimed invention.

Conclusion

18. No claims are allowed.

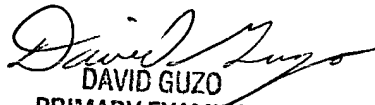
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly A. Makar, Ph.D. whose telephone number is 571-272-4139. The examiner can normally be reached on 8AM - 4:30 PM.

Art Unit: 1636

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KAM/07/16/06


DAVID GUZO
PRIMARY EXAMINER